

## ABSTRACT

### POSITIVE DETECTION LATERAL-FLOW APPARATUS AND METHOD FOR SMALL AND LARGE ANALYTES

5

Methods and devices for the detection and/or quantification of an analyte in a sample are provided. These are positive detection methods and devices, in that the more analyte is present in the sample, the stronger the signal that is provided. Devices of the invention include a mobilization zone including a mobile or mobilizable detectable analyte analog, a sample application area, primary and secondary capture areas each including an immobilized binding partner having a binding affinity for the analyte being tested for a detectable analyte analog. The mobilization zone, sample application area, primary and secondary capture area are in fluid continuous contact with each other. In these devices, the first immobilized binding partner has an equal or lower apparent affinity for the analyte than it has for the detectable analyte analog. Methods of this invention involve introducing a sample (which is suspected of containing the analyte to be tested for) to a device such as those described herein, and permitting the sample to migrate from the application area to and through the first and secondary binding zones. A detectable tracer conjugate is also permitted to migrate through the device, usually slightly behind the sample so that any analyte in the sample contacts the first binding partner before the conjugate. Results of such methods are read based on the presence and/or intensity of the detectable signal given by conjugate that binds in the second capture area.

10

15

20